SciReg, Inc.
Science and Regulatory Consultants

October 24, 2013

Ms. Kimberly Nesci
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application
- Helicovex
- Andermatt Biocontrol AG

Dear Ms. Nesci:

On behalf of Andermatt Biocontrol AG, SciReg, Inc. is submitting a new product registration application for Helicovex, an end-use product containing 0.6% *Helicoverpa armigera* nucleopolyhedrovirus, strain BV-0003 (HaNPV). In support of this application, Andermatt is submitting generic and product-specific data and information and citing existing HzNPV data.

As agreed during the April 23, 2013 preregistration meeting and reiterated in the associated meeting minutes (attached), below is a discussion of the submitted data and the associated active ingredient.

Currently, there is one EPA-registered product that contains *Helicoverpa zea* NPV, which is the same as *H. armigera* NPV, Gemstar LC (EPA Reg. No. 70051-45).

The following characteristics of baculoviruses are outlined in OECD Consensus Document No. 20 (submitted herein), which was developed under the OECD Working Group on Biotechnology.

- Baculovirus species are extremely host-specific, with their host range limited to one or a few species of the same genus. Larger host ranges covering different genera or even different families are rare. Baculoviruses probably represent the most specific pesticidal agents, biologicals and chemicals taken together.

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- Baculoviruses occur only in arthropods, predominantly in the insect orders *Lepidoptera*, *Diptera*, and *Hymenoptera*.
- Baculoviruses are not infective to mammals and replication does not occur in mammalian cells.
- No pathogenic, genotoxic, mutagenic, or carcinogenic effect of baculoviruses has ever been observed in mammals.
- Baculoviruses do not produce metabolites since they have no independent metabolism.
- Effects on non-target species can be excluded, especially for vertebrates, micro-organisms, and plants.

It is thoroughly established that baculoviruses are neither toxic, nor pathogenic. Andermatt Biocontrol is, therefore, submitting and citing data and information on *Helicoverpa armigera* NPV, as well as other baculoviruses, in support of its registration of Helicovex.

As there is an existing tolerance exemption for nuclear polyhedrovirus of *Helicoverpa zea,* 40 CFR Part 180.1027 and, as such, although the proposed product will be used on food crops and is considered to contain a new active ingredient, it was determined during the preregistration meeting that this regulatory action falls under PRIA Category B612 – New active ingredient; no change to a permanent tolerance exemption. The corresponding PRIA fee is $16,714. Andermatt qualifies for a 50% PRIA fee reduction; supporting company and financial information is included herein. A copy of the electronic payment receipt for $8,357.00 is enclosed.

If you have any questions regarding the application materials, please let me know.

Sincerely,

Patricia Biggio

Patricia Biggio
Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Andermatt Biocontrol AG
Stahlermatten 6
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Switzerland

SciReg, Inc. *
12733 Director's Loop
Woodbridge, VA 22192

* SciReg, Inc. is the authorized agent for Andermatt Biocontrol AG.

Regulatory action in support of which this package is submitted

New Product Registration: Helicovex

Transmittal Date

October 24, 2013

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	Volume 1	Administrative Materials
49239301	Volume 2	Product Identity, Manufacturing Process, Deposition of a Sample in a Nationally Recognized Culture Collection, and Discussion of the Formation of Unintentional Ingredients (OCSPP 885.1100, 885.1200, 885.1250, and 885.1300)
49239302	Volume 3	Analysis of Samples and Certified Limits (OCSPP 885.1400 and 885.1500)
49239303	Volume 4	Summary of the Physical-Chemical Properties (OCSPP 830.6302 - 830.7300)
49239304	Volume 5	Physical-Chemical Properties: Color, Physical State, Odor, pH, Viscosity, and Density (OCSPP 830.6302, 830.6303, 830.6304, 830.7000, 830.7100, and 830.7300)
49239305	Volume 6	Physical-Chemical Properties: Storage Stability, and Corrosion Characteristics (OCSPP 830.6317 and 830.6320)
49239306	Volume 7	Hypersensitivity incidents (OCSPP 885.3400)
49239307	Volume 8	Cell Culture Waiver Request (OCSPP 885.3500)
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49239310	Volume 11	Nontarget Insect Toxicity – Aphids (OCSPP 885.4340)
49239311	Volume 12	Nontarget Organism Waiver Request (OCSPP 885.4100, 885.4150. 885.4280, 885.4300)

Company Official: Patricia Biggio

Company Name: SciReg, Inc.

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